NOT FOR PUBLICATION

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEW JERSEY

NOSTRUM PHARMACEUTICALS, LLC, Plaintiff, v. UNITED STATES FOOD AND DRUG ADMINISTRATION, Defendants.	Civil Action No. 11-3111 (JAP) **OPINION**

PISANO, District Judge.

Plaintiff Nostrum Pharmaceuticals, LLC ("Nostrum" or "Plaintiff") brings this action challenging certain decisions of the United States Food and Drug Administration ("FDA" or "Defendant") relating to Nostrum's Abbreviated New Drug Application ("ANDA") for carbamazepine 300 mg extended-release capsules. Nostrum alleges that the FDA incorrectly determined that Nostrum's statutory exclusivity period for marketing its generic carbamazepine product has expired as to U.S. Patent No. 5,912,013 ("the '013 patent") and may be shortened as to U.S. Patent 5,326,570 ("the '570 patent") by reason of pending expiration of that patent. Apotex Inc. ("Apotex"), a subsequent ANDA filer for carbamazepine extended-release capsules, has intervened in the matter as a defendant. Presently before the Court is a motion by Nostrum for a preliminary injunction enjoining the FDA from approving any competing carbamazepine ANDAs until after November 16, 2011, on which date Nostrum will have had the full statutory 180 days of marketing

exclusivity. Alternatively, Nostrum seeks an order enjoining the FDA from approving competing ANDAs without advance notice to both Nostrum and the Court sufficient to permit Nostrum to move the court for relief to protect its exclusivity. The FDA and Apotex have filed opposition the motion. The Court heard oral argument on the motion June 27, 2011, and Plaintiff has requested the Court issue an expedited decision in light of the time-sensitive nature of the issues in order to allow it to take a prompt appeal. For the reasons below, Nostrum's motion is denied.

I. Background

A. Generic Drug Approval Process

Under the Federal Food, Drug, and Cosmetic Act ("FDCA"), the FDA is authorized to regulate the manufacture, distribution, and sale of drugs in the United States. In accordance with the FDCA, pharmaceutical companies seeking to market new drugs (often referred to as "pioneer" or "branded" drugs) must first obtain FDA approval by filing a new drug application ("NDA") containing extensive scientific data demonstrating the safety and effectiveness of the drug. U.S.C. §§ 355(a), (b). An NDA applicant must also submit information on any patent that claims the drug, or a method of using the drug, and for which a claim of patent infringement could reasonably be asserted against an unauthorized party. 21 U.S.C. §§ 355(b)(1), (c)(2). The FDA publishes this patent information in the "Approved Drug Products with Therapeutic Equivalence Evaluations" list, commonly known as the "Orange Book." *Id.*; *see also* 21 C.F.R. § 314.53(e).

The approval of generic drugs is governed by the FDCA as modified by the Drug Price Competition and Patent Term Restoration Act of 1984 (the "Hatch-Waxman Amendments"), codified at 21 U.S.C. § 355 and 35 U.S.C. §§ 156, 271, and 282. These

amendments were designed to balance the interests of encouraging innovation in the development of new drugs and accelerating the availability of lower-cost generic alternatives to branded drugs.

Under the Hatch-Waxman Amendments, a manufacturer submits an abbreviated new drug application ("ANDA") requesting approval of a generic version of an approved drug product. 21 U.S.C. § 355(j). The ANDA must include, among other things, data showing that the generic drug product is the bioequivalent to the branded drug product. 21 U.S.C. § § 355(j)(2)(A)(iv); (j)(4)(F). With respect to Orange Book listed patents for the branded drug, an ANDA must contain one of four certifications:

> (I) that such patent information has not been filed,
> (II) that such patent has expired,
> (III) …the date on which such patent will expire, or
> (IV) that such patent is invalid or will not be infringed by the manufacture, use, or sale of the new drug for which the application is submitted.

21 U.S.C. § 355(j)(2)(A)(vii). This certification is typically referred to as a "paragraph I," "paragraph II," "paragraph III," or "paragraph IV" certification.

An applicant wishing to challenge the validity of a patent or to claim that the patent would not be infringed by the product covered by the ANDA submits a paragraph IV certification. The filing of a paragraph IV is an act of infringement, 35 U.S.C. § 271(e)(2)(A), and if a suit is brought within 45 days of receipt of notice of the certification by the patent owner or NDA applicant, the FDA must stay approval of the ANDA for up to 30 months. 21 U.S.C. § 355(J)(5)(B)(iii). If no action is brought within the requisite period, the FDA may approve the ANDA immediately. 21 U.S.C. § 355(J)(5)(B)(iii).

To encourage generic drug companies to bear the costs and potential risks associated with submitting a paragraph IV certification, the Hatch-Waxman Amendments provide a "180-day exclusivity period" to the applicant who is the first to file an ANDA containing a paragraph IV certification. 21 U.S.C. § 355(j)(5)(B)(iv). During this period, the applicant who is the first to file may market its product while FDA approval of all other ANDAs covering the same product are delayed. Under the statutory provisions relevant to this action,[1] the 180 period begins to run the earlier of (1) the first commercial marketing of the generic drug by the first ANDA filer; or (2) "the date of a decision of a court … holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv) (2002).

B. Nostrum's ANDA

The relevant facts in this matter are undisputed. Shire Development Inc. ("Shire") is the reference listed drug manufacturer for carbamazepine extended-release capsules, marketed under the brand name Carbatrol. Two patents are listed in the Orange Book for Carbatrol: the '013 patent and the '570 patent.

On March 26, 2003, Nostrum was the first to file an ANDA for the 300 mg strength of carbamazepine containing paragraph IV certifications as to the '013 and '570 patents. On September 18, 2003, Shire commenced patent infringement litigation against Nostrum. *Shire Labs. v. Nostrum Pharms. Inc.*, Civil Action No. 03-4436-MLC (D.N.J.). In 2006, the matter was stayed and, thereafter, the stay was extended a number of times. On March

[1] Congress amended 21 U.S.C. § 355(j) in 2003. *See* The Access to Affordable Pharmaceuticals provisions of the Medicare Prescription Drug, Improvement, and Modernization Act of 2003, Pub. L. No. 108-173, 117 Stat. 2066 (Dec. 8, 2003) (the "MMA"). Because Nostrum's application was submitted before the December 8, 2003 enactment date of the amendments, pre-MMA exclusivity provisions apply in this case.

22, 2010, the parties ultimately settled. This settlement included a license giving Nostrum the right to sell carbamazepine extended release capsules on or after October 1, 2010. According to Nostrum, it was prepared to market its generic product as of that date; however, its release was subject to FDA approval, which had not yet been granted.

Nostrum's ANDA received final FDA approval on May 20, 2011. In its approval letter, the FDA recognized that Nostrum was the first to file an ANDA for carbamazepine containing a paragraph IV certification as to the '013 and '570 patents and, therefore, was eligible for the 180-day exclusivity period. Mulye Decl. Ex. A at 2. However, the FDA determined that such exclusivity would be based only upon the '570 patent because, as the FDA advised Nostrum, it concluded that the exclusivity period for the '013 patent had been triggered by a 2009 judgment in the matter *Shire Labs, Inc. v. CorePharma, LLC,* Civil Action 06-2266 (D.N.J.). *Id. Shire* was a patent infringement action in which the court had granted a motion for summary judgment and entered final judgment in favor of defendant CorePharma LLC on July 14, 2009. Thus, according to the FDA, upon approval of Nostrum's ANDA, the exclusivity period for the '013 patent had long since expired.

Nostrum began marketing its product immediately upon approval and, as such, there is no dispute that the start of the exclusivity period as to the '570 was triggered on that date. The '570 patent expires on July 23, 2011.[2] *See* Notice at D.I. 30. It is the FDA's position that, for reasons described more fully below, upon expiration of the '570 patent any later-filed carbamazepine ANDA that is otherwise eligible for approval may be approved after that date.

[2] The parties originally believed and had advised the Court that the patent expired on July 5, 2011. A recent filing with the FDA by the patent holder provided the corrected date.

II. Analysis

Nostrum's challenge to the FDA's action is two-fold. First, Nostrum argues that the FDA's determination that the '013 patent exclusivity period was triggered by the 2009 *CorePharma* decision reflects an incorrect application of the relevant standard. Second, Nostrum argues that the FDA's determination that it may approve competing ANDAs upon expiration of the '570 patent and thereby cut short Nostrum's exclusivity period is contrary to the governing law. In its complaint, Nostrum seeks declaratory and injunctive relief. By way of this motion, Nostrum seeks a preliminary injunction barring the FDA from approving competing ANDAs for 300 mg carbamazepine until at least November 16, 2011. In the alternative, Nostrum seeks an order enjoining the FDA from approving subsequently filed ANDAs without first providing notice to Nostrum and the Court sufficient to permit Nostrum to move this Court for relief "to protect Nostrum's exclusivity period." Pl. Br. at 36.

When evaluating a motion for preliminary injunctive relief, a district court must consider: "(1) whether the movant has shown a reasonable probability of success on the merits; (2) whether the movant will be irreparably injured by denial of the relief; (3) whether granting preliminary relief will result in even greater harm to the nonmoving party; and (4) whether granting the preliminary relief will be in the public interest." *McTernan v. City of York*, 577 F.3d 521, 526 (3rd Cir. 2009). A preliminary injunction "should not be granted unless the movant, by a clear showing, carries the burden of persuasion." *Masurekv. Armstrong*, 520 U.S. 968, 972, 117 S.Ct. 1865, 138 L.Ed.2d 162 (1997). Preliminary injunctive relief is an "extraordinary and drastic remedy", *id.*, which "should issue only if the plaintiff produces evidence sufficient to convince the district court

that all four factors favor preliminary relief." *American Tel. and Tel. Co. v. Winback and Conserve Program, Inc.*, 42 F.3d 1421, 1427 (3d Cir. 1994). "The burden lies with the plaintiff to establish every element in its favor, or the grant of a preliminary injunction is inappropriate." *P.C. Yonkers, Inc. v. Celebrations the Party and Seasonal Superstore, LLC*, 428 F.3d 504, 508 (3d Cir. 2005). Because, as set forth below, the court finds that Nostrum has failed to establish its likelihood of success on the merits, the court addresses only that element in its analysis.[3]

A. Standard of Review Under the APA

This Court reviews the FDA's administrative decisions under the Administrative Procedure Act ("APA"). The Court must uphold such decisions unless they are "arbitrary, capricious, an abuse of discretion, or otherwise not in accordance with law." 5 U.S.C. § 706(2)(A). This is a very narrow and highly deferential standard under which an agency's action is presumed valid. *Citizens to Preserve Overton Park v. Volpe*, 401 U.S. 402, 415, 91 S.Ct. 814, 28 L.Ed.2d 136 (1971); *Clean Ocean Action v. York*, 861 F.Supp. 1203, 1219 (D.N.J. 1994). A reviewing "court is not empowered to substitute its judgment for the agency's." *Citizens to Preserve Overton Park*, 401 U.S. at 416, 91 S.Ct. 814. Instead, the court's inquiry is limited to determining whether the agency "considered the relevant factors and articulated a rational connection between the facts found and the choice made," *Baltimore Gas & Elec. Co. v. Natural Res. Def. Council, Inc.*, 462 U.S. 87, 105, 103 S.Ct.

[3] However, were the Court to reach the irreparable harm prong of the analysis, it appears that Plaintiff would be unable to establish that element as well. As the FDA notes, Nostrum's claim of harm is based on a loss of exclusivity and can only occur if and when the FDA approves a subsequent carbamazepine ANDA. The FDA has advised that, at least as of the date of oral argument, there are no pending carbamazepine ANDAs that have been even tentatively approved. Thus, it is speculative whether Nostrum would face competition between July and November 2011.

2246, 76 L.Ed.2d 437 (1983), and "whether there has been a clear error of judgment." *Motor Vehicle Mfrs. Ass'n of U.S., Inc. v. State Farm Mutual Auto. Ins. Co.*, 463 U.S. 29, 43, 103 S.Ct. 2856, 77 L.Ed.2d 443 (1983). An agency's conclusions will be upheld "if they are supported by such relevant evidence as a reasonable mind might accept as adequate to support a conclusion." *Passaic Valley Sewerage Comm'ns v. U.S. Dept. of Labor*, 992 F.2d 474, 480 (3d Cir.1993); *see also Friends of the Earth v. Hintz*, 800 F.2d 822, 831 (9th Cir.1986) ("The court may not set aside agency action as arbitrary or capricious unless there is no rational basis for the action.").

Where the review involves an agency's interpretation of a statute, a court applies the deferential two-part framework of *Chevron U.S.A. Inc. v. Natural Res. Def. Council, Inc.*, 467 U.S. 837, 104 S.Ct. 2778, 81 L.Ed.2d 694 (1984). Under *Chevron*, a court must first determine "whether Congress has directly spoken to the precise question at issue." *Chevron*, 467 U.S. at 842, 104 S.Ct. 2778. If the intent of Congress is clear, the unambiguously expressed intent of Congress must be given effect. *Id.* at 843, 104 S.Ct. 2778. However, "[i]f the statute is silent or ambiguous with respect to the specific issue, the question for the court is whether the agency's answer is based on a permissible construction of the statute." *Id.*

B. '013 Patent – Court Decision Trigger

As noted above, the pre-MMA version of the FDCA that governs this case contains two potential "triggers" for the commencement of the 180-day exclusivity period: the first commercial marketing of the product, or an applicable court decision. The so-called "court decision trigger" provides that exclusivity begins to run on "the date of a decision of a court in an action described in clause (iii) [*i.e.*, a patent infringement case

triggered by the notice of a paragraph IV certification] holding the patent which is the subject of the certification to be invalid or not infringed." 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002). Following the decision in *Teva Pharmaceuticals USA, Inc. v. FDA*, 441 F.3d 1 (D.C. Cir. 2006), the FDA has interpreted the court decision trigger to require "a decision of a court that on its face evidences a holding on the merits that a patent is invalid, not infringed, or unenforceable" (referred to herein as the "holding-on-the-merits" standard). *See* Letter from G. Buehler to Apotex Corp. (April 11, 2006), FDA Ex. B. Purportedly applying this standard, the FDA determined that the 2009 final judgment in *Shire Labs, Inc. v. CorePharma, LLC*, triggered exclusivity as to the '013 patent. *See* 2008 WL 4822186, Civil Action 06-2266 (D.N.J. November 3, 2008). Consequently, by the time Nostrum's ANDA received final approval, the FDA determined its 180-day exclusivity on the '013 patent had expired. Nostrum challenges the FDA's determination, arguing that the *CorePharma* decision was not a court decision under 21 U.S.C. § 355(j)(5)(B)(iv)(II) (2002) for purposes of triggering 180-day exclusivity with respect to the '013 patent.

The *CorePharma* case was a Hatch-Waxman infringement suit involving the '570 and '013 patents. The original complaint in the action included claims for infringement of both the '570 and '013 patents, but an amended complaint filed one day after service of the original complaint omitted the claims as to the '013 patent. In answering the amended complaint, CorePharma included a counterclaim for declaratory judgment of noninfringement of the '013 patent.

CorePharma moved for judgment on the pleadings of noninfringement of the '013 patent, and Shire cross-moved to dismiss the counterclaim, arguing that there was no justiciable case or controversy over the '013 patent and that the court thus lacked subject

matter jurisdiction. The court in the *Corepharma* decision described the basis of Shire's jurisdictional argument:

> In its reply brief, Shire stated:
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> > Shire further assured Corepharma [] that infringement of the '013 patent was no longer at issue – Shire repeated its statements of noninfringement in its Reply, Brief in support of this Motion, Plaintiff's Brief in Opposition to Defendant's Motion for Judgment on the Pleadings, and in communications between counsel. These facts must not be ignored.
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> > ***
> >
> > In addition to Shire's representations of noninfringement made before this Court, Shire has provided Corepharma with an unconditional covenant not to sue. Such a covenant is, on its own, sufficient to moot a patent-based declaratory judgment action.
>
> Shire stated that it provided Corepharma with the following covenant:
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> > [Shire] unconditionally represents, stipulates, agrees and covenants that it will not sue Corepharma [] for infringement, or otherwise assert, enforce, or hold Corepharma liable for infringement of Shire's U.S. Patent No. 5,912,013 based on the importation, use, sale, or offer for sale of the extended-release carbamazepine capsules that are the subject of and described in Corepharma's ANDA 78-159 as disclosed to Shire as of September 1, 2006. This disclosure is limited to the materials sent by Corepharma to Shire under a cover letter dated April 25, 2006, as well as Corepharma's Notice of Patent Certification with attachment, dated March 30, 2006.

Shire Labs, Inc., 2008 WL 4822186 at *1-2. The *CorePharma* court granted Shire's motion and dismissed the counterclaim for lack of subject matter jurisdiction. *Id.* at *2.

Subsequently, the Federal Circuit issued its decision in *Caraco Pharm. Labs., Ltd. v. Forest Labs., Ltd.*, 527 F.3d 1278 (Fed. Cir. 2008), in which the court found that a

unilateral covenant not to sue provided to an ANDA applicant from a patent holder did not render moot a declaratory judgment action over a patent. In light of *Caraco*, the *CorePharma* court vacated its order dismissing the counterclaim. CorePharma then filed a motion for summary judgment of noninfringement of the '013 patent.

In support of its summary judgment motion, CorePharma argued that "Shire has no evidence of infringement and cannot prove it." *Shire Labs, Inc.*, 2008 WL 4822186 at *4. CorePharma relied primarily on the argument that judicial estoppel precluded Shire from defeating the motion. *Id.* As the court noted, Shire took several inconsistent positions with respect to the motion:

> 1) the previous position that Corepharma's ANDA products do not infringe the '013 patent is inconsistent with the present position that Corepharma's ANDA products do infringe the '013 patent; 2) the previous statement to the Court that Shire has unconditionally promised not to assert that Corepharma's ANDA products infringe the '013 patent is inconsistent with the present arguments that Corepharma's ANDA products infringe the '013 patent; and 3) the previous statement to the Court that Shire's unconditional promise encompassed the product samples Corepharma gave Shire in April of 2006 is inconsistent with Shire's present use of evidence derived from those samples.

Id. Ultimately, the court found that judicial estoppel precluded Shire from contesting infringement of the '013 patent. *Id.* at *10. The court held as follows:

> Because Shire has been judicially estopped from contesting infringement of the '013 patent, Corepharma's motion for summary judgment is unopposed. *This Court finds that Shire has no evidence and cannot prove that Corepharma has infringed the '013 patent. Corepharma is entitled to judgment of noninfringement of the '013 patent as a matter of law.* The motion for summary judgment will be granted.

Id. (emphasis added). Final judgment based upon this decision was entered on July 14, 2009, and the FDA determined that exclusivity was triggered as of that date.

Nostrum does not challenge the FDA's interpretation of the court decision trigger; that is, it does not challenge the correctness of the "holding-on-the-merits" standard applied by the FDA. Indeed, courts addressing the issue have upheld the FDA's "holding-on-the-merits" standard. *See, e.g.*, *Apotex, Inc. v. FDA*, 449 F.3d 1249 (D.C. Cir. 2006). Rather, Nostrum contends that FDA applied that standard incorrectly here. As noted above, this standard requires "a decision of a court that on its face evidences a holding on the merits that a patent is invalid, not infringed, or unenforceable." Nostrum argues that because the *CorePharma* court judicially estopped Shire from arguing that CorePharma's product infringed the '013 patent after Shire had previously conceded non-infringement, the court's grant of summary judgment in favor of CorePharma was more akin to a dismissal for lack of jurisdiction than a decision on the merits of infringement. According to Nostrum, a holding on the merits of infringement requires a court to compare the accused product to the asserted claims and conclude, based upon the comparison, that the ANDA product does not infringe.

The Court is unconvinced by Nostrum's argument. As an initial matter, the FDA has never interpreted the court decision trigger provision to require a court to compare the claims of the asserted patents to the accused generic product. Rather, the FDA has interpreted the statute's express requirement of a court decision "holding the patent which is the subject of the certification to be invalid or not infringed" as resolution of the issues of validity, infringement and enforceability "on the merits." Letter from G. Buehler to Apotex Corp. (April 11, 2006), FDA Ex. B at 7. Nothing suggests that the only way a court can reach a decision "on the merits" of an infringement claims is in the manner suggested by Nostrum. Indeed, in the context of a motion for summary judgment a court is

called upon to examine evidence, weigh substantive arguments and perform legal analysis. The court must determine whether there exists a genuine dispute of material fact and whether the undisputed facts entitle a party to judgment as a matter of law. Addressing such a motion, the *CorePharma* court concluded that there were no facts from which infringement could be found and entered judgment of noninfringement of the '013 patent as a matter of law. The FDA need not look any further than that.

Nostrum's approach would have required the agency to look beyond the face of the decision itself and is contrary to the FDA's interpretation of the court decision trigger provision, which sought to have exclusivity triggering determinations "governed by a legal regime that is clear and easily administered." *Id.* at 14. The holding-on-the-merits standard "provide[s] a bright line that is more easily administrable by FDA and … enable[s] industry to make appropriate business planning decisions. *Id.* at 2. A goal of the FDA's holding-on-the-merits approach is to "enable the agency to rely on the face of the court's decision to determine whether there has been a holding that a patent is invalid, not infringed, or unenforceable." *Id.* at 9. This is what the FDA did here. The *CorePharma* court granted CorePharma's motion for summary judgment, ruling that Shire "has no evidence and cannot prove that Corepharma has infringed the '013 patent." 2008 WL 4822186 at *10. It further ruled that CorePharma was therefore "entitled to judgment of noninfringement of the '013 patent as a matter of law." *Id.* Relying on the face of the decision, the FDA concluded that the decision constituted a holding on the merits that the '013 patent was not infringed.

The Court finds the *CorePharma* decision at issue in this case to be similar to the grant of partial summary judgment recognized as the triggering decision by the FDA in

Granutec, Inc. v. Shalala, 139 F.3d 889, 1998 WL 153410 (4th Cir. Apr. 3, 1998). *See* Letter from G. Buehler to Apotex Corp. (April 11, 2006) at 12, FDA Ex. B ("The underlying decision in *Granutec* was a memorandum decision granting a motion for partial summary judgment of noninfringement based on the patentee's concession that the defendant's product did not infringe."); Memorandum Decision, *Glaxo, Inc. v. Boehringer Ingelheim Corp.*, No. 95-01342 (D. Conn Oct 7, 1996), Wettre Decl. Ex. B. As noted by the court in *Apotex, Inc. v. FDA*, 2006 WL 1030151 (D.D.C. April 19, 2006):

> The *Granutec* court granted partial summary judgment, through a memorandum opinion, in one party's favor *on the basis of representations that had estoppel effect.* By its very nature, summary judgment requires the weighing of substantive arguments and necessitates legal analysis -- the court is required to determine that there is no genuine dispute of material fact, and the moving party is entitled to prevail as a matter of law. …In *Granutec*, the court was called upon to make a factual and legal finding with respect to the substantive arguments presented on the issue of patent invalidity, infringement, or unenforceability. … [T]he parties in *Granutec* could never have obtained the outcome in that case -- partial summary judgment -- without a court decision addressing the merits.

Id. at 15 (emphasis added). Likewise, the *CorePharma* court here entered summary judgment in favor of CorePharma, and ruled on the merits that the '013 patent was not infringed.

Finally, the Court is not persuaded by Nostrum's argument that, if the *CorePharma* decision triggered the running of Nostrum's exclusivity, the exclusivity has expired only as to CorePharma and not any other later ANDA applicants. Although Nostrum argues that there are "[s]everal strong policy reasons" that support such an outcome, Nostrum cites no authority for its novel interpretation of the statute. The relevant statutory provision prevents the FDA from approving "*the* application" of a subsequent ANDA filer until 180 days after "the date of a decision of *a* court in *an action* … holding the patent … to be …

not infringed." 21 U.S.C. § 355(j)(5)(B)(iv) (2002) (emphasis added). Nowhere does the provision suggest that it is applicable only to the ANDA applicant that was successful in obtaining the triggering decision. Nostrum's interpretation would, in essence, rewrite the statute.

In light of the above, the Court concludes the FDA's determination was an appropriate application of its holding-on-the-merits standard and, therefore, Nostrum has failed to establish that it has a likelihood of success on the merits of its claim. As such, the Court finds preliminary injunctive relief is not appropriate and denies Plaintiff's motion as to the '013 patent.

C. Expiration of the '570 Patent

As noted earlier, the '570 patent expires on July 23, 2011. According to Nostrum, it has been the FDA's policy under the pre-MMA exclusivity provisions applicable to this action that "when a patent that forms the basis … marketing exclusivity expires, so too does a first-filer's 180-day marketing exclusivity with respect to that patent." Pl. Brf. at 23. More specifically, it is the FDA's position that on July 24, 2011 (the day after expiration of the '570 patent), any applicant with a pending carbamazepine ANDA that contains a paragraph IV certification on the '570 patent will amend its certification to a paragraph II to accurately reflect the status of the '570 patent. *See* 21 C.F.R. § 314.94(a)(12)(viii)(C) ("[A]n applicant shall amend a submitted certification if, at any time before the effective date of the approval of the application, the applicant learns that the submitted certification is no longer accurate.") As such, the FDA asserts that there will no longer be any basis to delay approval of otherwise approvable later-filed ANDAs, because

the statute only permits FDA to delay approval for those applications containing a paragraph IV certification.

Nostrum contends such an interpretation of the relevant law is flawed because it divests a first-filer of its full 180 days of marketing exclusivity. In support of its argument, Nostrum relies upon the plain language of the exclusivity provision of the Hatch-Waxman Amendments, which Nostrum argues does not limit exclusivity to patent terms. The statute states in the relevant part as follows:

> If the application contains a certification described in subclause (IV) of paragraph (2)(A)(vii) [*i.e.*, a paragraph IV certification] and is for a drug for which a previous application has been submitted under this subsection [containing][4] such a certification, the application shall be made effective not earlier than one hundred and eighty days after—
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> (I) the date the Secretary receives notice from the applicant under the previous application of the first commercial marketing of the drug under the previous application, or
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> (II) the date of a decision of a court in an action described in clause (iii) holding the patent which is the subject of the certification to be invalid or not infringed,
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> whichever is earlier.

21 U.S.C. § 355(j)(5)(B)(iv) (2002) (footnote added).

In making its "plain language" argument that exclusivity is not limited to the term of the patent, Nostrum relies on the provision in the statute that that reads "the application shall be made effective not earlier than one hundred and eighty days after …." According to Nostrum, this provision entitles it to a full 180 days of marketing exclusivity, regardless

[4] The statute actually reads "continuing," but this appears to be a typographical error. Courts have noted that it probably should read "containing." *See Purepac Pharm. Co. v. Friedman*, 162 F.3d 1201, 1203 n.3 (D.C. Cir. 1998); *Mova Pharmaceutical Corp.*, 140 F.3d at 1064 n. 3.

of whether a subsequently-filed ANDA changes to a paragraph II certification. However, as the FDA points out, Nostrum's argument ignores opening phrase of the relevant provision -- "[i]f the application contains [a paragraph IV certification]." Once a patent has expired, an ANDA must be amended so that the paragraph IV certification to that patent becomes a paragraph II certification. 21 C.F.R. § 314.94(a)(12)(viii)(C); *see also Dr. Reddy's Laboratories, Inc. v. Thompson*, 302 F. Supp. 2d 340, 354 (D.N.J. 2003) (rejecting challenge to FDA's regulatory requirement that ANDA applicants change paragraph IV certifications to paragraph II certifications upon expiration of the relevant patent); *Mylan Labs., Inc. v. Thompson*, 332 F. Supp. 2d 106, 122 (D.D.C. 2004) (upon expiration of the relevant patent, an ANDA applicant must change paragraph IV certification to paragraph II certification or the FDA could treat paragraph IV certification as a paragraph II certification); *Ranbaxy Labs. Ltd. v. FDA*, 307 F. Supp. 2d 15 (D.D.C. 2004) ("[A]t that "magic moment," midnight on [the patent expiration date], the Paragraph IV certifications became invalid, and either converted as a matter of law to Paragraph II certifications or became inaccurate, thereby creating both an obligation on [the ANDA applicant's] part to amend its ANDAs to reflect patent expiry and an inability on the part of the FDA to approve the ANDAs in their inaccurate form.). Indeed, an application that contains an untrue statement of material fact cannot be approved. 21 U.S.C. 355(j)(4)(K).

Thus, upon expiration of the '570 patent, later-filed carbamazepine ANDAs will no longer "contain[]" paragraph IV certifications. By its plain terms, once this occurs, § 355(j)(5)(B)(iv) becomes inapplicable. There will no longer be any basis for the FDA to delay approving any of the later-filed ANDAs that otherwise would be eligible for approval. *See Mylan Labs., Inc. v. Leavitt*, 484 F. Supp. 2d 109, 122-23 (D.D.C. 2007)

(rejecting the argument that "nothing in the text or legislative history of the Hatch–Waxman Act indicates that generic exclusivity is forfeited upon patent expiration" in light of the statutory scheme that provides that once "a patent has expired, those applications with paragraph II certifications (including those converted from paragraph IV certifications) are eligible for immediate drug approval").

Prior courts addressing issues similar to the one raised here have ruled that the 180-day exclusivity period expires along with the underlying patent. *See generally* S. Upadhye, Generic Pharmaceutical Patent and FDA Law § 13:6. This Court agrees. The statutory provision entitling Nostrum to exclusivity, by its terms, applies only to paragraph IV certifications, "which cease to exist upon patent expiration." *Mylan*, 484 F. Supp. 2d at 123. Applying step one of *Chevron*, the Court finds the FDCA unambiguously supports the FDA's determination that it is not prohibited by 21 U.S.C. § 355(j)(5)(B)(iv) (2002) from approving later-filed ANDAs upon expiration of the '570 patent. As such, Nostrum has failed to establish the likelihood of success on the merits of its claims as to the '570 patent.

D. Alternative Relief

As stated earlier, as an alternative for an injunction enjoining the FDA from approving any competing carbamazepine ANDAs until after November 16, 2011, Nostrum has asked the Court for an order enjoining the FDA from approving competing ANDAs without first providing notice to Nostrum and the Court sufficient to permit Nostrum to move this Court for relief "to protect Nostrum's exclusivity period." Pl. Br. at 36. The Court denies that request for the reasons above and, further, because Nostrum has not

established that the Court is empowered to fashion such relief given the existing confidentiality concerns that relate to pending ANDA applications.

III. Conclusion

For the reasons above, Plaintiff's motion for a preliminary injunction is denied. An appropriate order accompanies this Opinion.

/s/ Joel A. Pisano
JOEL A. PISANO, U.S.D.J.

Dated: July 5, 2011